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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,602	09/08/2003	Enrique Zudaire Ubani	41743.8001.US00	6049

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EXAMINER
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SIMS, JASON M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/658,602	Applicant(s) ZUDAIRE UBANI ET AL.	
	Examiner Jason M. Sims	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 29-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election with traverse of Group II, claims 9-28, in the reply filed on 7/20/2006 is acknowledged. The traversal is on the ground(s) that the claimed inventions are not mutually exclusive as they stem from the same principal and that the various numbers of amplicons, primers, dyes, and calculations are variants of the claimed inventions. This is not found persuasive because the related inventions are distinct if the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions using varying number of amplicons, primers, and dyes constitutes materially different design and the use of different calculations constitutes unique modes of operations, functions, and effects. Therefore, some common limitations are not persuasive as the invention as a whole is being evaluated for examination distinctness.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-8 and 29-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected non-elected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/20/2006.

Claims 9-28 are the current claims hereby under examination.

### ***Specification***

The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable codes, found at pages 20, 21, and 32. Applicant is

required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 contains the wording, in parts B and C, "the second emission" and "a second emission," which is vague and indefinite as to what it refers. For example, it appears in part b "a second emission" refers to the emission measurement taken at a second temperature that is between the annealing/extension temperature and the  $T_m$  and is an emission measurement for the first amplicon. Additionally, in part c, line 2, "the second emission" appears to refer to the second emission measurement taken for the first amplicon whereas "a second emission" and "the second emission" stated in the last two lines of claim 9, appear to refer to the emission measurements of the second amplicon. With regards to the use of the words "a second measurement" and "the second measurement," clearer claim wording is required to clearly distinguish between emission measurements taken for the first amplicon and those taken for the second amplicon.

Claims 10 and 20 also contain the wording "the second emission," which is vague and indefinite as to what it refers. It appears that "the second emission" may

refer to the first amplicon, which has a different mathematical approach to determining an emission amount, which requires calculating a difference between two emissions, similar to that stated in the instant claim 10, which is different than the method for determining an emission amount for the second amplicon, which is simply determined by taking a second emission measurement for the second amplicon. Clearer claim wording is required.

Claims 9, 10, 15-19, 21, and 26-27 contain the acronym "MT," which is vague and indefinite. MT is not found to be a common acronym used in the art and needs to be defined in the claim language itself.

Claims 11-14, 20, 22-25, and 28 are rejected as being dependent from a rejected claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 9-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Wittwer et al. (US P/N 6, 472,156).

The claims are directed to a method of real-time detecting and quantifying a first nucleic acid template and a second nucleic acid template in a PCR mixture comprising the steps of thermally cycling a PCR mixture, obtaining first and second emissions, and determining the first and second emission amounts.

Wittwer et al. teaches claims 9 and 21, at col. 1, lines 13-22, col. 2, lines 25-67 and col. 3, lines 1-37, col. 3, lines 40-67, col. 4, lines 1-18, lines 31-35, lines 42-47 . Wittwer et al., at col. 1, discusses how the invention relates to multiplex PCR using differential fluorescent emission and differential hybridization melting temperatures, which allows simultaneous analysis. Wittwer et al., at col. 2 and col. 3, discusses step a of claims 9 and 21, a thermal cycling method, using a thermostable polymerase, dyes that binds to double stranded DNA and multiple primers and probes for amplifying multiple sequences of DNA. Wittwer et al. discusses, step b of claims 9 and 21 and claim 10 at col. 3 and col. 4, using at least 2 probe pairs where one member of each pair differentially hybridizes to different alleles and measuring the emission of each of the members at a first temperature and repeating those emission measurements at a second and third temperature, which represents obtaining cycle by cycle at a first MT and a second MT the emissions. Wittwer et al. further discusses part c of claims 9 and 21 in col. 4 at lines 28-35 and 42-47, the different hybridizations having different

emissions at different Tms and determining the different emissions based on the different Tms, which represents determining cycle by cycle a first emission amount and a second emission amount.

Wittwer et al. teaches claims 11, 12, 22, and 23 at col. 3, lines 4-7. Wittwer et al. discusses the background to PCR using nucleic acid binding dyes such as ethidium bromide and SYBR Green I, which are double stranded DNA intercalating dyes.

Wittwer et al. teaches claims 13 and 24 at col. 11, lines 66-67 and col. 12, lines 1-5. Wittwer et al. discusses using a PCR primer as a "probe-primer," which represents the double stranded DNA dye as being a primer-based double stranded DNA dye.

Wittwer et al. teaches claims 14 and 25 at col. 12, lines 15-20. Wittwer et al. discusses acceptable fluorophore pairs for use as fluorescein and rhodamine among others.

Wittwer et al. teaches claims 15-19 and 26-27 at col. 15, lines 60-67 and col. 16, lines 1-45. Wittwer et al. discusses emission measurements being made every 50 to 10,000 msec and the temperature between measurements varying by 0.01 degrees Celsius per second to 5 degrees Celsius per sec or varying by 0.5 or 1.0 degrees Celsius per second. Wittwer et al. discusses how initial temperatures for initial emission measurements are made at low temperatures and subsequent emission measurements are made at higher temperatures until at least melting temperatures. Therefore the increased increments of temperature ranges ensures at least 3 or more emission measurements, which represents increasing the temperature at which emission measurements are taken in the markush ranges specified in the instant claims.

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Wittwer et al. teaches claims 20 and 28 at col. 25, lines 65-67. Wittwer et al. discusses using the Lightcycler software for PCR and melting curve analysis, which represent a computer program for calculating first and second emissions.

### **Conclusion**

No claim is allowed

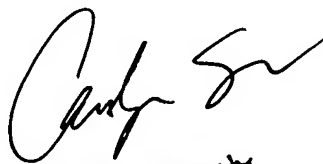
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Yolanda Chadwick, whose telephone number is (571)-272-0514.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
AV 1631 examiner  
10/2/06